OCT 27 2003

510(k) Summary for Swiss Master Light®

1. SPONSOR

EMS ELECTRO MEDICAL SYSTEMS SA
Ch. de la Vuarpillière 31
CH - 1260 Nyon
Switzerland

Contact Person: Suzanne Fassio-Hardy
Telephone: 022 994 47 00

Date Prepared: October 8, 2003

2. DEVICE NAME

Proprietary Name: Swiss Master Light®
Common/Usual Name: dental curing light
Classification Name: ultraviolet activator for polymerization

3. PREDICATE DEVICES

- Optilux 501 (K020091)
- Elipar® TriLight (K984247)

4. INTENDED USE

The Swiss Master Light® is a dental curing light that is designed for use in the photopolymerization of dental resins, activation of tooth whitening agents in bleaching procedures.

5. DEVICE DESCRIPTION

The Swiss Master Light® consists of a control unit with a handpiece connected to the Main Unit by a detachable handpiece cord. The handpiece contains the halogen light source and a light guide that directs light to the treatment area on the patient. The control unit provides power and cooling water to the handpiece and controls handpiece function.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

Both the proposed Swiss Master Light® and the predicate curing lights offer multiple curing programs for photopolymerization of dental resins and activation of bleaching materials. These programs differ in the intensity of the light delivered and the length of the light exposure.

The operational principles of the proposed and predicate devices are identical. The operator chooses the appropriate program and sets the treatment parameters, if necessary. The tip of the handpiece is oriented appropriately relative to the material being photopolymerized, or the tooth surface (for bleaching procedures), and the selected treatment is initiated.

The major difference between the proposed Swiss Master Light® and the predicate curing lights is the intensity of the light power delivered. The increased light intensity of the proposed Swiss Master Light® allows the resin curing and tooth whitening agent activation to be conducted in a much shorter timeframe. Performance testing has been conducted that confirms that the halogen light technology used for the Swiss Master Light® is able to cure resin and activate tooth bleaching agents within the specified timeframe without causing thermal damage to the tissue.

The similarities in intended use, technical specifications, and functional performance between the Swiss Master Light®, Optilux 501, and Elipar® TriLight curing lights leads to a conclusion of substantial equivalence between the proposed and predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 27 2003

E.M.S. Electro Medical Systems SA
C/O Cynthia J. M. Nolte, PhD., RAC
Staff Consultant
Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K032099
Trade/Device Name: Swiss Master Light®
Regulation Number: 21 CFR 872.6070
Regulation Name: Ultraviolet Activator for Polymerization
Regulatory Class: II
Product Code: EBZ
Dated: October 08, 2003
Received: October 10, 2003

Dear Dr. Nolte:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

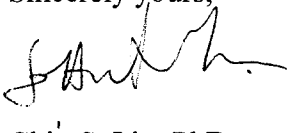
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



for, Chiu S. Lin, PhD
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): **K032099**

Device Name: Swiss Master Light®

Indications for Use:

The Swiss Master Light® is a dental curing light that is designed for use in the photopolymerization of dental resins, activation of tooth whitening agents in bleaching procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K032099

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)